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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,213	10/30/2000	James D. McIninch	04983.0220.00US00/38-10(1	6072

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ARNOLD & PORTER  
IP DOCKETING DEPARTMENT; RM 1126(b)  
555 12TH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/02/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/698,213

Applicant(s)

MCININCH, JAMES D.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2002
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 17-40 are cancelled as set forth in Paper No. 19, filed 2/27/03.

Applicant's arguments in Paper No. 19, filed 2/27/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims herein under examination are claims 1-16 and 41-44.

#### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **LACK OF ENABLEMENT**

The rejection of claims 1-16 and 41-44 is maintained under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-16 and 41-44 are rejected because the specification, while being enabling for the following:

Initial oligonucleotide probability

p. 21, equation I,

Transition probability	p. 22, equation II,
Nucleic acid sequence probability	p. 23, equation III, and
Probability for each nucleotide state	p. 24, equation IV,

the specification does not reasonably provide enablement for any method of computation for determining the above probabilities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant application fails to provide guidance to one of ordinary skill in the art for generating the probability values of the following by any other means than by the four equations indicated above. The specification does not provide or suggest what any other substitutable methods of computation could be for the above probability determinations thus not enabling one of ordinary skill in the art to know what calculations to perform. While the specification provides some guidance for a method of determining a probability value for the above listing using the particular equations or values disclosed, the specification does not provide guidance for a method of determining the probability by any other means. The specification does not provide working examples of the methods described using any other means of computing the described probability values. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of descriptive working examples in the specification, and the unpredictability of generating probability values, the specification as filed is not enabling for any method of determining the listed probability values as claimed. The instant application is only enabled for the above-mentioned computational means of the four probabilities.

This rejection is reiterated from the previous Office Action and maintained for reasons of record.

Applicant states that Examiner cites claims are enabled for four equations given in the specification and four particular bias values (Response, page 2, lines 12-15). The Examiner made no mention of bias values being enabled; however, the particular equations for biases that are listed in the specification, such as Equation V (page 24), are enabled.

Applicant argues that the specification need not provide *any* computational method that is used to perform the method steps of the present invention. This is found unpersuasive, because as written, the claims encompass *any* computational method that can be used to perform the method steps of the present invention. One of skill in the art would know how to use the method steps with the four above-mentioned enabled probability equations, but not with undisclosed equations. Applicant states it is wrong to suggest every possible permutation of computation to be specifically disclosed in the application. It is agreed that not every possible permutation of computation needs to be specifically disclosed; however, at least representative species outlining a broad scope of computational practices considered essential matter must be disclosed.

Applicant remarks that computational methods that already exist in the art should also be enabled but do not support such methods as well known. This is found unpersuasive, especially if the Applicant desires to include such essential material into the claimed invention to support a broad and generic practice. As stated in the previous Office action, page 5, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. It is noted that applicant's reliance on prior art methods may only

extend to well known methods and that single specific publications do not support their content as being well known.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-16 and 41-44 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 11 contain a mathematical equation which is confusing as it incorporates " $\Phi(f)$ " representing bias which cancels itself out in each equation, and therefore nullifies its effect on the equation. Applicant does not understand this rejection. However, if one of skill performs a simplification of the equation, the " $\Phi(f)$ " cancels itself out. In essence, Applicant is claiming something that cancels out and therefore does not exist. If the Applicant intends this bias not to be represented by the same exact number in the numerator and denominator, then subscripts, or some other form of notation, would need to be added to clarify this issue.

Claim 1 recites the phrase "said probability of said nucleic acid sequence" which is vague and indefinite due to the lack of clear antecedent basis for the noted phrase in part d) of claim 1. The only probability that is previously set forth in the claim is in part c) wherein apparently several probabilities are determined. That is, part c) determines a probability for said nucleic acid sequence for each of said states. This apparently is a plurality of probabilities, one for each state. Therefore, which probability is utilized in part d) of claim 1 which requires usage of apparently a singular "probability of said nucleic acid sequence"? Applicant rebuttal seems to be

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referring to just one "probability of said nucleic acid sequence" when more than one apparently exists. Therefore, this rejection is maintained. This lack of antecedent basis and unclear wording is also present in other independent claims 7, 8 (regarding part d) said window probability), 41, 42 (part a) probability of a window), 43, and 44 (part d) said window probability). This rejection is also applicable to claims 2-6 and 9-16 which are claims dependent from said independent claims due to their direct or indirect dependence.

The following rejections under 35 U.S.C. 112, second paragraph, are reiterated from the previous Office Action and maintained for reasons of record.

Claims 1, 7, 8 and 41-44 are vague and indefinite due to the lack of clarity in the phrase "based upon" (i.e. claim 1, line 8). It is unclear as to what are the metes and bounds of the parameters that determine how much basis is included upon the determinations. Claims 2-6 and 9-16 are also indefinite due to their dependency from claims 1 and 8.

Applicant disagrees with the rejection under 35 U.S.C. 112, second paragraph, because the detailed computational methods given the specification would allow assessment of determining in step d) is based upon the probability and the bias. This is not found persuasive because the applicant still has not defined exactly what bases and to what degree they should be drawn upon to determine the probability of the instant invention. As set forth in the previous two actions, a clarification of the metes and bounds is required to improve the clarity of these claims.

The term "capable" in claim 7 is a relative term that renders the claim indefinite. The term "capable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Applicant alleges that "capable" is not indefinite because the skilled artisan could readily ascertain whether the "determining" step is capable of accepting a bias. This is not found persuasive because the determination of a probability requires a statistical model and any such model consists of equations which are inherently capable of accepting a bias, in various forms such as multiplicative or additive.

Claims 3 and 11 are vague and indefinite due to the lack of clarity in the following terms:  $f$ ,  $S$ ,  $P_f$ ,  $P_i$ , and  $\Phi$ . It is unclear as to what are the metes and bounds of these terms.

Applicant disagrees with the indefiniteness of  $f$ ,  $S$ ,  $P_f$ ,  $P_i$ , and  $\Phi$ , because they are clearly defined in the specification. As set forth in the previous action, a clarification of the metes and bounds is required, by listing in the claim the exact definition of each term in order to make clear whether definitions from the art should be utilized or those in the specification since, as argued by Applicant, art defined (not specification defined) methods are apparently heavily relied on by Applicant.

Claims 8 and 44 lack clarity in step c) due to the claim language "determining a probability for said window for each of said states." Claims 9-16 are also indefinite due to their dependency from claim 8.

Applicant states this phrase would be understandable to one of skill in the art. However, the phrase in the previous paragraph is confusing as a probability cannot be determined for a window, but rather the states found in the window. Careful consideration of the syntax, particularly the arrangement of prepositional phrases within the claims, will improve the coherence of the claims as well as the claimed invention. Additionally, Applicant alleges that the specification would make this phrase easily understandable but do not point to where this



exists in the specification. Thus, Applicant's argument is an allegation without factual support and therefore non-persuasive.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7-9, 12, 13, 15, and 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Borodovsky et al. (*Computers Chem.*, 1993).

This rejection is reiterated *in full* from the previous *two* Office Actions and maintained for reasons of record.

Applicant states that each and every element of a claim must appear in a single art reference and further cites claims 1, 8, and 41-44 as including the step based on a bias and claim 7 as including the phrase "capable of accepting a bias." Due to the confusion (see 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejection above) of " $\Phi(f)$ " effectively canceling itself out in the equations of claims 3 and 11, these equations are equivalent to the equations listed on page 129 (Borodovsky et al.). Being equivalent equations, if one probability (as provided by the Applicant) is "capable of accepting a bias" (claim 7, line 10), then the same probability stated by Borodovsky et al. (page 129) must also be capable of accepting a bias. Therefore, Borodovsky et al. anticipate the instant invention. Applicants believes the previously submitted reasoning for this 102(b) rejection was not reasserted which is not the case. It was reiterated and maintained in the

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previous and current Office action in the third paragraph under the "Claim Rejections - 35 USC § 102" heading. " $\Phi(f)$ " has been used as an example of bias to illustrate why Borodovsky et al. anticipate the above-mentioned claims. Thus, the  $\Phi(f)$  equation is deemed a specie within the above listed rejected claims.

### *Conclusion*

#### **No Claims Are Allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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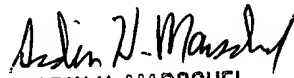
1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 30, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER